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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,667	07/24/2001	Andrew J. Goodearl	07334-130002	4858

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EXAMINER	
SOUAYA, JEHANNE E	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/911,667	GOODEARL ET AL.	
	Examiner	Art Unit	
	Jehanne E Souaya	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *24 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5/2003* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *1449: 1/2003* .

DETAILED ACTION

Specification

1. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

2. Claims 24 and 37 are objected to because of the following informalities: Claim 24 recites SEQ ID NO 12, however it appears that SEQ ID NO 2 was intended as SEQ ID NO 12 is a nucleic acid sequence, and not a polypeptide sequence. Claim 37 lacks the word "of" before the recitation of SEQ ID NO 3, which renders the claim grammatically incorrect.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 24-46 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The claims are drawn to an isolated nucleic acid molecule of SEQ ID NOS 1 and 3, and to nucleic acid sequences that encode the amino acid of SEQ ID NO 2, and to variants and fragments thereof. The claimed nucleic acids, vectors, host cells, and methods of using the

nucleic acids are not supported by a specific asserted utility because the disclosed uses of the nucleic acids are not specific and are generally applicable to any nucleic acid. The specification states that the nucleic acid compounds may be used to express a polypeptide, to identify identical, similar or related polynucleotides, to screen libraries or a plurality of molecules and compounds and to identify or to purify a ligand. These are non-specific uses that are applicable to nucleic acids in general and not particular or specific to the nucleic acid being claimed. The specification further states that the nucleic acids can be used as probes for detecting identical or related sequences. At page 51, the specification discloses that nucleic acid molecules of the invention can be used in screening assays, detection assays (such as chromosomal mapping and forensic biology), predictive medicine, and methods of treatment. At page 61, the specification teaches that the OCT1p sequences can further be used to provide polynucleotide reagents, ie probes, for use in hybridization techniques in forensic biology and for screening tissue culture for contamination. Furthermore, the specification fails to disclose a specific asserted utility of polynucleotide fragments, probes and primers of the claimed invention, because the use of the nucleic acid molecules of the claimed invention in hybridization assays and forensic biology are generally applicable to any nucleic acid and is therefore not particular to the isolated nucleic acid of the instant invention.

Further, the claimed nucleic acids, vectors, host cells, and methods of using the nucleic acids to produce a protein are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the protein. The need for such research clearly indicates that the protein and/or its

function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case, no substantial utility has been taught or demonstrated for the polypeptide of SEQ ID NO 2. The specification teaches that the invention is based on the discovery of a gene encoding OCT1p (OCT-like- protein) which is a transmembrane protein that is predicted to be a member of the superfamily of transporter molecules (p. 1, "Summary.."). However, without a teaching of what type of transporter, ie what types of molecules are transported by the OCT1p molecules, one skilled in the art would not know how to use the invention as claimed. Since the specification sets forth no specific function of the OCT1p molecule, the OCT1p gene or polynucleotide fragments have no ascribed function. The specification teaches that the OCT1p molecules of the present invention are useful as modulating agents in regulating a variety of cellular processes that depend on transport of biological molecules across a cellular membrane (p.2). The specification, however, does not teach or identify which specific cellular process or processes these are, and further does not teach how OCT1p would function in such undisclosed cellular processes. While the specification teaches that OCT1p is highly expressed in cells of the brain, tissue specific expression is not considered a specific or substantial utility absent a correlation between tissue specific expression and a specific disease, for example. A myriad of other proteins, with no structure or function in common with SEQ ID NO 2, would be expected to be expressed primarily in brain tissue, however the mere expression of such in brain tissue does not make a specific or substantial utility apparent for such polypeptides. While it might be inferred that proteins primarily expressed in brain tissue could be involved in cellular processes in the brain,

again, a myriad of cellular processes exist, and the mere expression of a polypeptide in brain tissue does not make the identity of which specific process it is involved in, readily apparent without extensive further research. While the specification contemplates that altering the expression or activity of OCT1p could alter the concentration of neurotransmitters, for example, to provide relief of symptoms of neurological disorders, central nervous system disorders, behavioral disorders, eating disorders, or sleeping disorders, the specification does not teach the specific function or activity of OCT1p, and whether enhancement or deletion of such function, or enhancement or a decrease in expression, would alter the concentration of neurotransmitters or any other molecule. Further, the specification does not teach which specific neurotransmitter or molecule would be affected, and how such would in turn provide relief from a specific disease. No direct connection is made between the claimed nucleic acids and any diseases that would be caused by a lack of expression or activity of OCT1p, nor has the specification taught what molecules are transported by OCT1p. The general listing of neurological diseases, central nervous system disorders, behavioral disorders, eating disorders, or sleeping disorders merely provides a laundry list of possible generic diseases or disorders (for example the use of the term "neurological diseases" is a broad term that in turn represents an extremely large list of different diseases and disorders each having different causes, symptoms, and which are affected by different cellular pathways) which could be associated in some way with OCT1p.

It is noted that the specification teaches OCT1p (SEQ ID NO 2) appears to be a human ortholog of rat SVOP, which is present in all areas of rat brain. However, neither the specification nor the art teach the specific function or activity of rat SVOP. Janz et al (Journal of Neuroscience, vol. 18, pp 9269-9281) teach that the closest relative of SVOP is a family of

organic anion and cation transporters, however Janz does not teach whether SVOP is a cation or anion transporter, or the identity of the specific molecules that SVOP transports. Further, neither the specification nor the art teach a universal correlation between members of this family, and a specific molecule transported, such that the skilled artisan would have a predictable correlation as to the specific function or activity of OCT1p or the identity of the specific molecule, it would be responsible for transporting. Further, Janz teaches that the sequence analysis of SVOP places it in the context of transport proteins, the analysis does not predict the nature of the transported molecule (see p. 9274, col 2, 2nd full para). Therefore, the similarity of OCT1p with SVOP that itself does not have a specific or substantial utility, does not provide a specific or substantial utility or a well established utility for the claimed nucleic acids.

The research contemplated by applicant(s) to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility of the utility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid and/or protein compound(s) such that another non-asserted utility would be well established for the compounds.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 24-46 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention because it cannot be determined from the specification what the specific function of the OCT1p molecules are (ie what type of a transporter is it, in other words what molecules is it responsible for transporting) or how aberrant expression or activity of the isolated OCT1p nucleic acid molecules of the instant invention would be useful for detecting the presence or susceptibility to any neurological diseases, behavioral disorders, and eating and sleeping disorders without undue experimentation.

7. Claims 24-29, 32, 33, and 38-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to isolated nucleic acid molecules having 85% or 95% identity with the nucleic acid sequence of SEQ ID NO: 1, to nucleic acid molecules 'comprising'

nucleic acid sequences encoding fragments (of at least 100, 150, or 300 contiguous amino acids, or polypeptides comprising amino acids 71-524) of SEQ ID NO:2, and to nucleic acids which hybridize to SEQ ID NOS 1 or 3. These claims encompass every mutant, variant, and homolog of the claimed SEQ ID NOS, from any source. However, the specification only teaches polynucleotides consisting of SEQ ID NOS 1 and 3 and teaches the amino acid sequence of SEQ ID NO 2. The claims encompass a large genus of nucleic acid variants, mutants, and homologs, from any source, for which a representative number have not been taught or described by the specification. The specification also fails to adequately describe the various fragments, mutants, and variants that are encompassed by the recitation of fragments in the claims. As no functional characteristics are taught by the specification that would distinguish the instant invention from other transport proteins, the skilled artisan would be unable to determine if a nucleic acid sequence was within the scope of the claims other than by SEQ ID NO. The mere fact that OCT1p could encode a transport protein does not provide any guidance or description as to critical or conserved amino acids required for function. Further, the specification does not teach what amino acids of SEQ ID NO 2 are critical for it's function and the skilled artisan would be unable to determine such as no specific function for OCT1p is taught by the specification.

Each of the claims represents a genus of nucleic acids for which a representative number of species for each genus must be disclosed to meet the written description requirement of 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow

persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NOS: 1, 2, and 3, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Conclusion

8. No claims are allowable.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703) 308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Primary Examiner
Art Unit 1634
6/30/03